

### REMARKS

The present application contains claims 1-206, the status of which is as follows:

- (a) Claims 7 and 11-15 are as originally filed.
- (b) Claims 6, 55-56, 60-64, 151, 155, 161-164, 166-168, and 172-177 were previously amended.
- (c) Claims 10, 59, and 205-206 have been currently amended.
- (d) Claims 152-154, 156-160, 165, and 169-171 were withdrawn in response to a restriction requirement.
- (e) Claims 1-5, 8, 9, 16-54, 57-58, 65-150, and 178-204 were previously canceled.

No new matter has been added. Reconsideration is respectfully requested.

Applicants thank Examiner Evanisko for the courtesy of a personal interview with the Applicant's representatives, Sanford T. Colb (Reg. No. 26,856) and Benjamin M. Fishman (Reg. No. 57,030), held in the USPTO on November 27, 2006 (Mr. Fishman participated telephonically). At the interview, Mr. Colb suggested amending independent claims 10, 59, 205, and 206 to delete the phrase "within a single heartbeat," in order to obviate the rejection of these claims under 35 U.S.C. 112, first paragraph. Instead, Mr. Colb suggested adding language to these claims that specifies that the signal "terminates during the refractory period," which the Examiner agreed has support in the specification. The Examiner also agreed that such amendments appear to overcome the rejections under 35 U.S.C. 102(e) and 103(a) over U.S. Patent No. 5,978,703 to Kroll et al.

Mr. Colb additionally suggested amending independent claims 10, 59, 205, and 206 to recite that the electrodes are "implantable." The Examiner agreed that such amendments appear to overcome the rejections under 35 U.S.C. 102(b) of claims 10 and 59 over U.S. No. Patent 5,205,284 to Freeman, and claims 205 and 206 over U.S. No. Patent 5,018,522 to Mehra.

Mr. Fishman and Mr. Colb argued that independent claims 10 and 59, as proposed to be amended, are patentable over U.S. No. Patent 6,141,586 to Mower. The Examiner stated that it appears that Mower does not apply to these claims, because Mower states that his first phase is subthreshold (col. 8, lines 55-59), but that the Examiner will perform a closer reading of the prior art to confirm that Mower has been accurately characterized by Applicants' representatives.

Finally, Mr. Colb agreed to file a supplemental IDS to correct the defects of the previously submitted IDS identified by the Examiner.

***Allowance of claims 6, 7, 55, and 56***

Applicants again thanks the Examiner for allowing claims 6, 7, 55, and 56 in the official actions dated October 19, 2005, and July 6, 2006.

***Rejections under 35 U.S.C. 112, first paragraph***

Claims 10-15, 59-64, 151, 155, 161-164, 166-168, 172-177, 205, and 206 were rejected under 35 U.S.C. 112, first paragraph, for failure to comply with the written description requirement. The Examiner argued that the phrase "within a single heartbeat" recited in independent claims 10, 59, 205, and 206 is not set forth in the specification as originally filed. Although Applicants strongly disagree with this rejection, Applicants have nevertheless amended these independent claims to remove the objectionable phrase, in order to expedite the issuance of a patent on subject matter believed to be allowable.

As mentioned above, Applicants have instead added the following feature to all of these independent claims: "wherein the cardiac muscle segments to which the one or more electrodes are applied are characterized by a refractory period, and wherein the overall duration of the signal is such that the signal terminates during the refractory period." This addition finds verbatim support in claims 5 and 53 as originally filed, and on p. 11 of the specification as originally filed. The Examiner suggested this addition on p. 10 of the current office action, and commented that this amendment finds support in the specification. Applicants thus submit that claims 10-15, 59-64, 151, 155, 161-164, 166-168, 172-177, 205, and 206 are now patentable under 35 U.S.C. 112, first paragraph.

***Rejections under 35 U.S.C. 102(e) over Kroll et al.***

Claims 10-13, 59-62, 151, 155, 161, 164, 166, 168, 172-173, and 175-177 were rejected under 35 U.S.C. 102(e) over U.S. Patent No. 5,978,703 to Kroll et al. The Examiner argued that Kroll et al. describe the application of a series of 10 pulses each having a duration of 1-5 ms, for a total duration of 10-50 ms. The Examiner further argued that each of the pulses causes a contraction of the heart, such that the total duration of 10-50 ms spans a plurality of heartbeats.

Applicants respectfully submit that the proposed amendment to independent claims 10, 59, 205, and 206 described above, that "the signal terminates during the refractory period," overcomes the rejection over Kroll et al. According to the Examiner, the signal of Kroll et al. comprises a series of signals, each of which includes a 1-5 ms pulse followed by 500 ms of dead time. Each of these 501-505 ms (1-5 ms plus 500 ms) signals terminates immediately prior to commencement of the following signal. Such a termination time point occurs substantially after the completion of the refractory period of the prior heart contraction. Applicants thus submit that claims 10-13, 59-62, 151, 155, 161, 164, 166, 168, 172-173, and 175-177 are patentable under 35 U.S.C. 102(e) over

Kroll et al. As mentioned above, the Examiner tentatively agreed during the interview that the claims, as proposed to be amended, appear to be novel over Kroll et al.

***Rejections under 35 U.S.C. 102(b) over Freeman***

Claims 10, 12, 13, 15, 59, 61, 62, 64, 151, 155, 164-167, 172, 173, and 177 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,205,284 to Freeman. The Examiner argued that Freeman shows a train of pulses having a duration of 20 to 150 ms. Freeman describes techniques for "transcutaneous, or external, electrical pacing of a patient's heart," for which it is well known to use substantially longer signals than are conventionally used for implantable pacemakers. As mentioned above, Applicants have currently amended independent claims 10 and 59 to recite that the electrodes are "implantable." This amendment finds support in Fig. 2 and throughout the specification as originally filed. Applicants respectfully submit that these claims are now allowable over Freeman, because there would have been no motivation to use the longer signal duration of Freeman's external pacemaker for an implantable pacemaker. As mentioned above, the Examiner agreed during the interview that this proposed amendment appears to overcome Freeman.

***Rejections under 35 U.S.C. 102(b) over Mehra***

Claims 205 and 206 were rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 5,018,522 to Mehra. Mehra describes an "external non-invasive cardiac pacemaker" that applies pulses having a 20 to 40 ms duration. As mentioned above, Applicants have currently amended independent claims 205 and 206 to recite that the electrodes are "implantable." As discussed above with respect to Freeman, there would be no motivation to use Mehra's external signal duration for an implantable pacemaker. Applicants thus respectfully submit that these claims are now allowable over

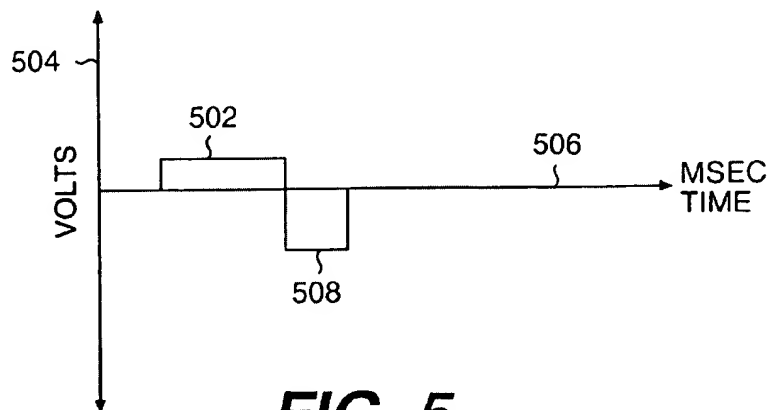
Mehra. As mentioned above, the Examiner agreed during the interview that this proposed amendment appears to overcome Mehra.

***Rejections under 35 U.S.C. 102(e) or 103(a) over Mower***

Claims 10, 12-15, 59, 61-64, 151, 155, 161, 162, 164, 166, 168, 172, 173, 177, 205, and 206 were rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over, US Patent 6,141,586 to Mower. The Examiner argued that Mower describes the application of a pacing signal having a duration of greater than 8 ms "from a time of initiation of application of the signal that initiates action potential" (p. 5 of the office action).

The Examiner's attention is drawn to Fig. 5 of Mower, and the description thereof in the specification. Mower describes a pacing signal that has two phases:

- "a first stimulation phase, comprising low level, long duration anodal stimulation 502 having amplitude 504 and duration 506"; and
- "This first stimulation phase is immediately followed by a second stimulation phase comprising cathodal stimulation 508 of conventional intensity and duration" (col. 8, lines 35-41, emphasis added).



***FIG. 5***

Mower's first phase has a subthreshold amplitude, that is, it does not cause action potential propagation, i.e., does not pace. The second phase initiates action potential propagation, i.e., paces. Mower states that the first phase may have a duration of between 2 and 8 ms, and the second phase may have a duration of between 0.3 and 1.5 ms.

In Mower, it is the second, cathodal stimulation phase that initiates action potential propagation. This second phase of Mower's signal has a duration of only 0.3 to 1.5 ms, i.e., a conventional duration, which is substantially less than the 8 ms recited in claims 10 and 59. Applicants thus submit that claims 10 and 59 do not read on Mower, because the signal recited has a duration greater than 8 ms "from a time of initiation of application of that portion of the signal that initiates action potential propagation."

The Examiner further argued that the first phase of Mower's signal is not necessarily subthreshold, i.e., of a strength insufficient to generate action potentials: "Although Mower says that the anodal portion [the first portion] could be subthreshold, this occurs in an 'alternative embodiment' (column 8, line 41)" (p. 5 of the office action).

Applicants respectfully submit that the Examiner has not correctly characterized Mower. It is true that the subthreshold option occurs in an alternative embodiment. However, in both of the relevant alternative embodiments (numbers 1 and 2), Mower describes the first phase of the signal as being subthreshold:

In differing alternative embodiments, anodal stimulation 502 is: 1) at maximum subthreshold amplitude; 2) less than three volts; 3) of a duration of approximately two to eight milliseconds; and/or 4) administered over 200 milliseconds post heart beat. Maximum subthreshold amplitude is understood to mean the maximum stimulation amplitude that can be administered without eliciting a contraction (col. 8, lines 41-48).

Several lines later, Mower again makes it clear that the first phase of stimulation is subthreshold: "In the manner disclosed by these embodiments, as well as those alterations and modifications which can become obvious upon the reading of this specification, a maximum membrane potential without activation is achieved in the first phase of stimulation" (col. 8, lines 55-59 [emphasis added]). Mower does not describe an embodiment in which activation is achieved during the first phase of stimulation.

The Examiner argued still further:

In addition, even if the alternative embodiment pulse of the first part of the pulse is subthreshold, the second part of the pulse does cause an action potential. Since any pulse delivered to a cell changes its action potential threshold, this will be the beginning/initiation of that portion of the signal that initiates action potential propagation. This is similar to what the applicant argues in the paper of 4/19/06 and what is described in the applicant's specification on page 17. If the overall duration of the pulse is greater than 8 ms, the first 1-2 ms of the pulse is what initiates the action potential, i.e., it is subthreshold since no action potential has resulted yet, which is similar to Mower's alternative embodiment subthreshold first phase of the pulse (p. 7).

Applicants respectfully disagree with the Examiner's arguments. First, even if it is assumed for the sake of argument that any pulse will change a cell's action potential threshold, it does not follow that Mower's first phase "initiates" action potential propagation, given that Mower explicitly states that the point of his first phase is to not generate action potentials. Second, Applicants never argued that the first 1-2 ms of the claimed signal initiates but does not actually cause an action potential, as the Examiner characterized the Applicants' previous response. This first portion of the Applicants' signal thus cannot accurately be characterized as "subthreshold."

In summary, Mower's goal is to (a) precondition the heart with his first, long stimulation phase (2-8 ms), *without pacing the heart*, and *thereafter* (b) to pace the heart with a conventional short pacing pulse of 0.3-1.5 ms. Thus, in terms of the language of claim 10, the duration of Mower's pacing signal measured "from a time of initiation of application of that portion of the signal that initiates action potential propagation" is 0.3-1.5 ms, which is substantially less than the 8 ms recited in claims 10 and 59.

For these reasons, Applicant submit that claims 10, 12-15, 59, 61-64, 151, 155, 161, 162, 164, 166, 168, 172, 173, 177, 205, and 206 are neither anticipated nor obvious over Mower. As mentioned above, during the interview the Examiner agreed that it appears that these claims do not read on Mower, subject to further consideration of Mower by the Examiner.

Dependent claim 167 was rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kroll. In light of the suggested patentability of claim 59, from which this claim indirectly depends, Applicants submit that claim 167, being of narrower scope, is allowable.

Dependent claims 163 and 167 were rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mower. In light of the suggested patentability of claim 59, from which these claims indirectly depend, Applicants submit that claims 163 and 167, being of narrower scope, are allowable.

Dependent claim 174 was rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. or Mower or Freeman. In light of the suggested patentability of claim 59, from which this claim indirectly depends, Applicants submit that claim 174, being of narrower scope, is allowable.



Independent claims 205 and 206 were rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. As discussed hereinabove with respect to claims 10 and 59, Applicants have amended claims 205 and 206 to recite that the pacing signal "terminates during the refractory period." In contrast, as mentioned above, the signal of Kroll et al. terminates substantially after the completion of the refractory period of the prior heart contraction. The Examiner's argument that it would have been obvious to substitute a single pulse for Kroll et al.'s train of pulses is thus moot, and claims 205 and 206 are thus in a condition for allowance.

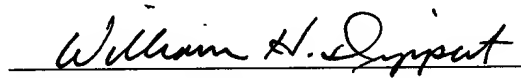
***Withdrawal of restriction requirement***

Claims 152-154, 156-160, 165, and 169-171 were withdrawn in response to a restriction requirement. Given the suggested patentability of independent claims 10 and 59, from which these non-elected claims directly or indirectly depend, the Applicant respectfully submits that the restriction requirement with respect to these withdrawn claims should be withdrawn (MPEP 821.04).

Applicants believe the amendments and remarks presented hereinabove to be fully responsive to all of the grounds of rejection raised by the Examiner. In view of these amendments and remarks, Applicant respectfully submit that all of the claims in the present application are now in order for allowance. Notice to this effect is respectfully requested.

Respectfully submitted,

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